**Steinbeis-Transferinstitut**
**Life Sciences Technologies**
**der Steinbeis University Berlin**

# Certificate

We hereby certify, that the below mentioned production lines meet

*all GMP-guidelines, EG –GMP-Annex 15 guideline*
*and PIC/S guideline PI 006-1 requirements.*

Product lines: **ID30 HMI-17“**

Manufacturer: Mettler-Toledo (Albstadt) GmbH
Unter dem Malesfelsen 34
72458 Albstadt
Germany

Tübingen, 1. Juli 2006

Prof. R. Ziegler

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# 1 Description of the product lines

## ID30 HMI-17“

Weighing terminals of the ID30 HMI-17“ family are robust and powerful industry PCs with an integrated, calibration capable weighing function. Open PC architecture is the base for the flexible solution of all sorts of tasks in weighing technology and data processing.
In principle, ID30 HMI-17“ pondering terminals consist of two units:
The so-called HMI-Box has a 17 Inch big, bright and very well readable Colour-TFT display and a pressure point membrane keyboard with number look and numerous function and weighing specific buttons. The HMI box is also availably with a Touch Screen. The Elo box contains the real PC and the weighing electronics and is built up very modularly. Through this the electronic components can be adapted to different requirements in a simple way. The Elo box can be equipped with up to ten interfaces; almost all connection standards are supported. Modern Windows operating systems allow a simple use of many communication and internet technologies. Individual customer applications and connection to modern ERP systems can be realized fast and simply. Both the HMI box and the Elo box are equipped with an IP69K protection way.



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# 2 General requirements of balances

Balances have to show the suitable measurement range and the required precision (EC-GMP guide, chapter 3.40).

They have to be calibrated regularly, what is to be documented (EC-GMP guide, chapter 3.41).

The permitted tolerance must be provided under consideration of the measuring inaccuracies, i.e. the still tolerated deviation of the debit value, for the respective weighing capacity.

The equipment used at the handling with the raw materials and utensils must meet the requirements for surfaces in the pharmaceutical production.

The FDA writes according to § 211.65 construction of the equipment: *„(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.*

The clean ability is confirmed by the cleaning validation. Established cleaning instructions are necessary as a prerequisite for a cleaning validation

The at most permitted spreading amount of active ingredients and cleaning agent is depending on the preliminary product, the derivative product and the lot size of the derivative product. A general statement for not critical products can be made with the criteria "visual clean". Due to respected and in the literature described tests a quantity in backlog of 375 µg per 100 $cm^2$ is no longer visible.



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# 3 Appraisal factors for an optimal cleaning

*General*

In principle, the parts which come in contact with the product, these are the burden plates of the balances, have to be cleaned well.

Both the FDA inspection guideline for cleaning validation and the PIC guideline PIC/S 006-1 name the visual criteria as acceptance criteria to appraise the cleaning success.
The balances of the product line ID30 HMI-17“ were subjected to a qualified examination regarding "clean ability". Therefore the criteria „visually clean“ was used. This means that the balances of the products ID30 HMI-17“ must be free of visible residua after cleaning. As a basis for this examination the works of Buscalferri, F., Assignation of the visibility limit of pharmaceutical active agents (“Bestimmung der Sichtbarkeitsgrenze von pharmazeutischen Wirkstoffen”), master thesis, Albstadt-Sigmaringen University, course of studies pharmaceutical technology (1999) and Fourman, G. L., Mullen, Determining Cleaning Validation Acceptance Limits for Pharmaceutical Manufacturing Operations , Pharm. Technol. 17 (4), 54 (1993) were used.

*Proceeding*

The weighing terminals of the product line ID30 HMI-17“ do not come in touch with the product; therefore a cast test was renounced. The display doesn't show any heavily accessible places. The Elo box, which contains the PC, is made of V2A steel and can be cleaned very easily with a soft cloth and a common cleaning agent.

*Summary*

The weighing terminals of the product lines ID30 HMI-17“ are GMP-compliant. There aren't any heavily accessible places in which dust could accumulate.



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# 4 Appraisal criteria for a qualification

*General*

The PIC/S guideline PI 006-1 and the EG-GMP guide Annex 15 mention principles for qualification and validation.
Every machine or equipment which directly or indirectly influences the quality of the product shall be qualified. The machine or equipment shall be designed in agreement with the prevailing GMP guidelines. The machine shall be installed in agreement with the design specification and the functions shall be checked with the available documentation (functional qualification

*Proceeding*

The available documentation of the product lines ID30 HMI-17“ were checked to the effect whether a design qualification, installation qualification, functional qualification and a computer validation is feasible.



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*Results*

The documentation of the weighing terminals ID30 HMI-17“ are very detailed. Detailed descriptions of the balances with design drawings are available. The used materials are described in detail.
GMP-relevant documents are available (e.g. inspection certificate, CE-mark). Details on the maintenance are listed.
The weighing terminals are equipped with a common operating system. For purposes of the quality control it is possible to receive a meaningful print out of the electronically stored data. This requirement is also mentioned in the EC-GMP Guide Annex 11 for computer validation.

*Summary*

The documentation of the weighing terminals ID30 HMI-17“ is very detailed and offers the necessary conditions for the execution of a qualification as it is demanded by EG-GMP guide Annex 15 and PIC/S guideline PI 006-1.



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